

law to administer or use the device or upon such other conditions as the Commissioner may prescribe.

(j) *Classification name* means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) *Representative sampling of advertisements* means typical advertising material that gives the promotional claims made for the device.

(l) *Representative sampling of any other labeling* means typical labeling material (excluding labels and package inserts) that gives the promotional claims made for the device.

(m) *Material change* includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

(n) *510(k) summary* (summary of any information respecting safety and effectiveness) means a summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(o) *510(k) statement* means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification

submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in §20.61 of this chapter.

(p) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(q) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

(r) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(s) *Wholesale distributor* means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001]

## Subpart B—Procedures for Device Establishments

### § 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing

of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term "device" includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.

(3) Repackages or relabels a device;

(4) Acts as an initial importer; or

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) No registration or listing fee is required. Registration or listing does not constitute an admission or agreement or determination that a product is a

device within the meaning of section 201(h) of the act.

(c) Registration and listing requirements shall not pertain to any person who:

(1) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;

(2) Sterilizes devices on a contract basis for other registered facilities who commercially distribute the devices.

(3) Acts as a wholesale distributor, as defined in §807.3(s), and who does not manufacture, repackaging, process, or relabel a device.

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in §1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of §807.31 remain applicable.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 58 FR 46522, Sept. 1, 1993; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 5466, Jan. 19, 2001; 66 FR 59160, Nov. 27, 2001]

#### **§ 807.21 Times for establishment registration and device listing.**

(a) An owner or operator of an establishment who has not previously entered into an operation defined in §807.20 shall register within 30 days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within 30 days after receiving registration forms from FDA. FDA will mail form FDA-2891a to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows: